Remarks

Status of the Claims and Support for the Amendments

By the foregoing amendments, claims 1-2, 5-6, 24, 36, 37, 59 and 60 are sought to be amended, new claims 110-139 are sought to be added, and claims 27-34, 78, 82-89 and 101-108 have been canceled without prejudice or disclaimer. Support for the amendments to the claims, and for new claims 110-139, can be found throughout the present specification, and in the claims as previously filed. Therefore, these amendments introduce no new matter, and their entry and consideration are respectfully requested.

Upon entry of the foregoing amendments, claims 1-21, 23-26, 35-38, 59-77, 79-81, 90-96, and 109-139 are pending in the application, with claims 1 and 59 being the independent claims. Claims 12, 16, 36-37, 68, 72, 91 and 92 have been withdrawn from consideration by the Examiner.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Statement of Substance of the Interview

Further to the Interview Summary provided to Applicants' undersigned representative on April 22, 2009, Applicants submit the following Statement of the Substance of the Interview.

Applicants thank Examiner Gupta for the personal interview conducted on April 22, 2009. During the interview, Applicants discussed the rejections of record. It was also discussed that Applicants will present a declaration demonstrating that the coupling chemistry utilized in the application is applicable to different proteins, peptides

and biological molecules similar to methoxy-PEGylation chemistry. Applicants will also present arguments that demonstrate that the PEG-diols are used as pharmaceutical excipients and thus side reactions would not take place with PEG-diols.

Summary of the Office Action

In the Office Action dated March 25, 2009, the Examiner has made three rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112 Second Paragraph

In the Office Action at page 2, the Examiner has rejected claims 1-11, 13-15, 17-27, 30, 35, 38, 59-67, 69-71, 73-82, 85, 90, 93-96 and 101-109 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. By the foregoing amendments, claims 27, 30, 78, 82, 85 and 101-108 have been canceled (Applicants note that claim 22 was canceled in a previous Reply). Hence, this rejection has been rendered moot as it may have applied to these claims. Applicants respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner contends that it is unclear how more than one bioactive component can be present in the conjugate when the claims recite that the PEG is attached to a single bioactive component. Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's contentions. However, solely to expedite prosecution, present claim 1 (and hence, claims 2-11, 13-15, 17-21,

23-26, 35, 38, 94-95, 109-117, 126-129 and 134-136 which ultimately depend therefrom) and present claim 59 (and hence, claims 60-67, 69-71, 73-77, 79-81, 90, 93, 96, 118-125, 130-133 and 137-139 which ultimately depend therefrom) recite conjugates comprising a bioactive component. Hence, Applicants respectfully submit that a person of ordinary skill in the art would readily understand the metes and bounds of the presently claimed invention, and thus, the present claims are not indefinite.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. § 112 First Paragraph, Written Description

In the Office Action at pages 3-8, the Examiner has rejected claims 1-11, 13-15, 17-27, 30, 35, 38, 59-67, 69-71, 73-82, 85, 90, 93-96, and 101-109 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. By the foregoing amendments, claims 27, 30, 78, 82, 85 and 101-108 have been canceled (Applicants note that claim 22 was canceled in a previous Reply). Hence, this rejection has been rendered moot as it may have applied to these claims. Applicants respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner states that:

> the claims are drawn to conjugates comprising one or more bioactive component[s] covalently attached to a linear or branched polyalkylene glycol. The base claim does not define the bioactive agent and subsequent dependent claims 27-31, while claiming specific biological agents, also claims mimic [sic] or functional agonist[s] of any of the specific peptides/proteins claimed. The generic statement of [a] biologically active agent or mimic of [sic] functional antagonist, does not

> provide ample written description for the compounds since the claims do not describe a single structural feature.

Office Action at page 5, second full paragraph. The Examiner further asserts that "the specific peptide/non-peptide bioactive components do not provide written description for all of the bioactive agents, mimetic[s], and functional antagonist[s] of the claimed invention." *Id.* at page 6, lines 9-11.

In response to Applicants' arguments made in the Reply to Office Action of November 20, 2007, the Examiner asserts that "it is unclear how pegylation technology can be used to provide written description for the claimed invention." *Id.* at page 7, last paragraph. The Examiner therefore concludes that the specification fails to provide adequate written description for the genus recited in the claims. Applicants respectfully disagree with the Examiner's contentions and conclusions.

As referenced by the Examiner, the MPEP lists several factors that can be used to determine if sufficient evidence of possession of an invention has been furnished in the disclosure of an application. One such factor is the "level of skill and knowledge in the art." *Id.* at page 4, second paragraph. In addition, as the Federal Circuit has held, the written description requirement must be viewed in light of the state of the art at the time of filing. *Capon v. Eshhar,* 418 F.3d 1349, 1357-1358 (Fed Cir. 2005) ("[t]he descriptive text needed to meet these [written description] requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.").

Other factors in the MPEP cited by the Examiner useful for determining whether a specification has met the Written Description requirement include partial structure,

physical structure and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Applicants respectfully submit that these requirements have been met in the present specification, as the structures, chemical properties, and functional characteristics of the recited protein/non-protein bioactive components were all well known at the time of filing, in the same way as the DNA sequences used to make the chimeric genes were known in *Capon. Id* at 1358.

Applicants respectfully submit that, as set forth in Applicants' Reply to Office Action filed November 20, 2007 (the disclosure of which is incorporated by reference herein in its entirety), at the time of filing of the present application, the level of skill and knowledge in the art of PEGylation technology was very high. As set forth below, the conjugation methods (i.e., conjugation of polymer to bioactive component) utilized in the practice of the present invention are the same as those utilized in traditional PEGylation technology. Thus, the ordinarily skilled artisan would have readily understood, based on the present specification viewed in the context of knowledge available at the time of filing of the present application, that any and all peptide/non-peptide bioactive components could be utilized in the practice of the presently claimed invention, as they are in traditional PEGylation technology.

As set forth in the present specification, "[a]s the ordinarily skilled artisan will appreciate, any bioactive component known and readily available in the art is suitable for conjugation with monofunctional polymers having reduced antigenicity, substantially reduced antigenicity or undetectable antigenicity, according to the present invention." Present specification at page 31, paragraph [0082]. Regarding the method of making the

presently claimed invention, Applicants respectfully submit that one of ordinary skill in the art of PEGylation technology, instructed by the disclosure of the present specification, would have been able to readily synthesize any number of hydroxy-polyalkylene glycolated compounds using well-known biochemical procedures (*see* discussion below regarding the rejection under 35 U.S.C. § 112, first paragraph, enablement). Therefore, the present specification clearly provides sufficient written description of the presently claimed invention.

The Examiner is reminded that Applicants are not required to describe an entire family of bioactive components that are already well known in the art. Rather, as held in *Capon*, when the art includes the relevant information, "precedent does not set a *per se* rule that the information must be determined afresh." *Capon,* 418 F.3d at 1358. In this light, Applicants are not required to disclose every bioactive peptide/non-peptide component that is useful in the present claims, since the art has previously recognized and reported the structures and functions of such bioactive components. *See also*, *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005) (holding that description of a single species is sufficient written description for claims directed to a modified polypeptide having DNA polymerase activity).

The present specification discloses at pages 26-32, numerous examples of bioactive components that can be used in the practice of the presently claimed invention. Furthermore, as set forth in the Declaration of Merry R. Sherman (hereinafter "the Sherman Declaration"), at pages 5-6, paragraphs 10 and 11, at the time of filing the '597 application, it was well known to artisans working in the area of PEGylation technology that numerous different types of bioactive components could be coupled to PEG

molecules using well-known chemical coupling reactions. For example, as described in Fishburn, *J. of Pharm. Sci. 97*:4167-4183 (2008) (hereinafter "Fishburn;" Exhibit C), "[t]he first five approved [PEGylated] products were proteins or peptides; the most recently approved, Macugen® (pegatanib), is an RNA aptamer, while studies on PEG-conjugates of small molecules such as the $\alpha 4\beta 1$ integrin inhibitor demonstrate that the technology can extend beyond biologics and macromolecules." Fishburn at page 4168, first column, first paragraph. Greenwald *et al.*, *Adv. Drug Del. Rev. 55*:217-250 (2003) (hereinafter "Greenwald;" Exhibit D) provides a review on the production of a number of PEG-bioactive component conjugates, including proteins such as α-interferon, bovine adenosine deaminase and L-asparaginase, for example. Greenwald at page 219, section 2.1. Greenwald also describes the PEGylation of a number of small organic molecules, such as doxorubicin, paclitaxel (*id.* at page 220, section 2.2), camptothecin (*id.* at page 225, first column, lines 1-4) and daunorubicin (*id.* at page 231, section 3.2.1. *See also* Rodrigues *et al.*, *Bioorg. Med. Chem. 7*:2517-2524 (1999) (Exhibit E), e.g., at abstract and introduction. In addition, as discussed in Greenwald, PEGylated conjugates of oligodeoxynucleotides have also been prepared (Greenwald at page 221, section 2.4), as well as PEG conjugates of antibodies and antibody fragments (*id.* at page 222, section 2.5).

Thus, it was well known by those of ordinary skill in the art that PEGylated conjugates could be prepared using an array of different bioactive components. Based on this knowledge, and the disclosure of numerous bioactive components throughout the present specification, one of ordinary skill in the art would clearly have understood that the present inventors were in possession of the full scope of the presently claimed

invention at the time of filing the application. Therefore, Applicants submit, in view of the holdings in *Capon* and *Invitrogen*, and the arguments presented above, the present specification clearly provides a sufficient description of the presently claimed invention to meet the requirements of 35 U.S.C. § 112, first paragraph.

With regard to the Examiner's reliance on *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997), Applicants note that *Lockwood* does not require *in haec verba* support for claimed subject matter. Only an "equivalent description" is necessary, and whether or not a description is "equivalent" is viewed from the standpoint of a person of ordinary skill in the art reading the specification in context of knowledge in the art. *Id.* at 1572.

The Examiner also contends that: "[t]here is no disclosure of a polymer with hydrogen bonding sites capable of promoting release of the active compounds." Office Action, page 6, lines 24-25. Applicants respectfully submit that this contention has no relevance to the present claims. The presently claimed invention does not depend on "release" of the bioactive component from the polyalkylene glycol moiety. In fact, the present specification discloses *covalent* bonding of a polyalkylene glycol moiety to the bioactive component. *See* claims 1, 54, and Specification at pages 3-5, 11, 13, 17 and 24. Covalent bonding of the polyalkylene glycol moiety to the bioactive component maximizes therapeutic efficacy as described in the present specification by increasing the serum half life of said bioactive component, and hence release of the bioactive component from the polyalkylene glycol moiety is neither required nor desired. *See* present specification at page 3, paragraph [0005]. In addition, the Examiner notes "[t]he specification is limited to the above mention[ed] cyclic molecules that share a common

core." *Id.* at page 6, lines 23-24. Applicants note that this also appears to have no relevance to the present claims, as nowhere is there any mention of cyclic molecules having a common core in the practice of the presently claimed invention.

The Examiner also cites *In re Wilder*, 736 F.2d 1516, 1521, for the contention that the present specification provides only an indication of a result that one might achieve if one made the invention. Office Action at page 7, lines 1-2. Applicants respectfully submit that the present specification clearly does more than simply outline the goals Applicants hope to achieve. The Applicants in *Wilder* simply set forth their desired goals in the Object of the Invention section. *see* 736 F.2d at 1521. In contrast, as noted above, the present specification clearly provides a full description of the presently claimed conjugates, including methods of preparing such conjugates, active components that can be used in preparing such conjugates, as well as the conjugates themselves. Thus, the present specification clearly provides a sufficient written description of the presently claimed invention.

Hence, when viewed in light of the state of the art at the time of filing the present application, the ordinarily skilled artisan would readily recognize that the present specification fully supports the presently claimed invention, and that Applicants were in full possession of the presently claimed invention at the time of filing. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are therefore respectfully requested.

Rejections under 35 U.S.C. § 112 First Paragraph, Enablement

In the Office Action at pages 8-13, the Examiner has rejected claims 1-11, 13-15, 17-27, 30, 35, 38, 59-67, 69-71, 73-82, 85, 90, 93-96 and 101-109 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. By the foregoing amendments, claims 27, 30, 78, 82, 85 and 101-108 have been canceled (Applicants note that claim 22 was canceled in a previous Reply). Hence, this rejection has been rendered moot as it may have applied to these claims. Applicants respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner characterizes the state of the art of PEGylation technology as follows:

> The art states that one of the hydroxyl groups of the PEG is converted to mono-functional methoxy-PEG since high diol concentration will yield unwanted cross-linking conjugates. Monofunctionality of methoxyPEG makes it particularly suitable for protein and peptide modification because it yields reactive PEGs that do not produce crosslinked polypeptide, as long as diol PEG has been removed. Roberts states that a promising strategy for generating heterobifunctional PEGs [sic] and using them in polymerization. The art has recognized PEG groups with a hydroxyl group at one terminus and amino group at the other end or PEG groups with formyl group on one end and hydroxyl group at the other end. However, Roberts states that "[t]his strategy also has its limits. Only those anions that are desirable as end groups and suitable for initiating polymerization are useful for synthesis of *heterobifunctional* PEG by this route. This method is also limited by the fact that rigorous exclusion of water is necessary to prevent formation of the diol.

Office Action at paragraph bridging pages 9-10.

The Examiner also states that "[g]iven the state of the art with respect to diol and crosslinking, it is highly unpredictable to form a PEG conjugate with one biological agent." *Id.* at page 10, lines 6-7. Furthermore, the Examiner asserts that:

> The specification, however, does not provide any examples that demonstrate the coupling of a heterobifunctional PEG, with a free hydroxyl group, to a protein, especially GM-CSF. Such guidance is necessary because the art indicates that the strategy utilizing heterobifuncatioal [sic] PEG, that have a free hydroxyl group, also has its limits. . . . This method is also limited by the fact that rigorous exclusion of water is necessary to prevent the formation of the diol. . . . Further, the art recognizes that when PEG-diol is present, unwanted crosslinking occurs. . . . This claim language seemingly excludes crosslinked proteins. However, without protection of the free hydroxyl or how to prevent formation of diol, a crosslinked product would occur.

Id. at page 11, lines 3-18.

In response to Applicants' arguments presented in their Reply to Office Action of November 20, 2007, the Examiner states that:

> it is unclear how the state of the art can be of assistance when the claimed invention use PEG diols that have, unlike applicants['] assertions, two hydroxyl functionalities prior to conjugation to the bioactive molecule. . . . For this reason, the prior art utilizes non-aqueous reaction systems. Here the specification calls for aqueous reaction systems that use PEG diols. Given the art, one would expect unwanted crosslinking reactions to occur.

Id. at page 12, lines 13-19. The Examiner therefore concludes that the presently claimed invention is not enabled. Applicants respectfully disagree with the Examiner's contentions and conclusions.

Applicants respectfully submit that the Examiner appears to be confusing the preparation of the polyalkylene glycol molecules (e.g., PEG) of the present invention with the conjugation of these molecules to a bioactive component. As set forth in detail in the Sherman Declaration, at pages 7-11, the conjugates of the presently claimed invention are generated by first preparing the monofunctionally activated polyalkylene glycol molecule (for example, as described in the '597 application at pages 21-26, and

Examples 5 and 6), and then conjugating the polyalkylene glycol molecule to a bioactive component (*see e.g.*, the '597 application at pages 33-38, and Examples 1 and 7). As stated at page 21, paragraph 60 of the '597 application, and in the Sherman Declaration at pages 7-11, preparation of the conjugates of the present invention requires simply "substitution of such monofunctionally activated PEGs in place of monofunctionally activated mPEG" in well-known PEG conjugation methods. Thus, those of skill in the art would readily recognize that the conjugation between the hydroxyl terminated polymers of the presently claimed invention and the bioactive components, is suitably performed in the same manner as the conjugations traditionally performed using mPEG (or other alkoxyl-terminated polymers) and the same bioactive components.

As described throughout the '597 application, including throughout pages 33-38, and Examples 1 and 7, conjugation of the polyalkylene glycol molecules of the present invention to the bioactive component, utilizes well-known, well-characterized coupling reactions. "The PAGs employed in the practice of the present invention, which, as indicated above, are preferably activated by reaction with a coupling group, can be attached to any of several groups that may be present on the bioactive component molecule . . . ." '597 application at page 33, paragraph [0084]. Applicants respectfully submit, as detailed in the Sherman Declaration, these conjugation reactions (as well as others known in the art) would not have required undue experimentation to perform, and simply required the substitution of the monofunctionally activated polymers of the present invention in place of the art-known alkoxyl-terminated polymers, in the conjugation methods.

Regarding the Examiner's contention that the present specification does not provide sufficient enabling examples, Applicants note that Example 5, at page 59-61, provides a full procedure for producing monofunctional hydroxy-polyalkylene glycol molecules (*e.g.*, PharmaPEG®). As set forth at pages 5-6, paragraph [0009], Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that such polyalkylene glycol molecules could be readily coupled to various bioactive components to form conjugates such as PEG-GM-CSF, PEG-adenosine deaminase, PEG-superoxide dismutase (SOD), and PEG-urate oxidase. *See* Specification at page 5, paragraph [0009], pages, 33-38, and Examples 1 and 7. Applicants note that the methods of forming such conjugates were well-known in the art, for example as taught in the incorporated references recited in paragraph [0009], and as detailed in the Sherman Declaration at pages 7-11. Furthermore, the present specification at pages 33-38 and Examples 1 and 7, provides ample guidance with regard to specific reaction conditions useful to conjugate polyalkylene glycol molecules to bioactive components. Hence, preparations of the various conjugates of the presently claimed invention would not have required undue experimentation.

Applicants respectfully remind the Examiner that a specification is presumed to be enabling unless the Examiner provides acceptable objective evidence or sound scientific reasoning showing that it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. *See In re Marzocchi*, 439 F.2d 220 (C.C.P.A. 1971). Moreover:

> [t]he purpose of [the enablement] provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue

> experimentation, relying on the patent specification and knowledge in the art.

Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1006 (Fed. Cir. 1991).

Furthermore, the proper standard of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the application, coupled with information known in the art, without undue experimentation. *See United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987). In addition, the question of undue experimentation is a matter of degree, and "the key word is 'undue,' not 'experimentation.'" *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), quoting *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976). In order to enable a claimed invention, a specification need not teach, and preferably omits, information that is well-known to those of ordinary skill in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 730 F.2d 1452, 1463 (Fed. Cir. 1984); *In re Wands*, 8 USPQ2d 1400, 1402 (Fed. Cir. 1988). In addition, one of ordinary skill in the art is deemed to know not only what is considered well-known, but also where to search for any needed starting materials. *See In re Howarth*, 210 USPQ 689, 692, (CCPA 1981).

As noted above, Applicants respectfully submit that the present specification clearly sets forth methods for the synthesis of monofunctionally activated polyalkylene glycol reagents, and methods for coupling the monofunctionally activated polyalkylene

glycol reagents to bioactive components, including reaction conditions, temperatures, pHs, and amounts and concentrations of reagents. *See* Specification at pages 33-38. Moreover, as is clearly disclosed in the present application, and detailed in the Sherman Declaration at pages 7-11, suitable methods for polyalkylene glycol activation and protein conjugation were well known to those of ordinary skill in the art at the time of filing of the present application (*see* present specification page 5, paragraph [0009], and pages 33-38). Applicants therefore submit that it would not have required undue experimentation to prepare the presently claimed hydroxyl-terminated polyalkylene glycol conjugates, using the guidance provided in the present specification (*see supra*). One of ordinary skill in the art would have readily recognized that the methods set forth in the specification would result in the synthesis of monofunctionally active hydroxyl-terminated polyalkylene glycols capable of covalently reacting in a non-crosslinking manner with a wide variety of bioactive components. While preparation of such conjugates may require some experimentation, a person of ordinary skill in the art would not consider such experimentation to be undue. The experiments and conditions set forth in the present specification would be considered routine by a person of ordinary skill in the art, and would require only very straightforward, simple assays.

Furthermore, the test of whether an amount of experimentation is undue is not merely quantitative; a considerable amount of experimentation is permissible, if it is merely routine (*i.e.*, uses methods known to those of ordinary skill in the relevant arts), or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *See PPG Indus., Inc. v.*

Guardian Indus. Corp., 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), citing *Ex parte Jackson*, 217 USPQ 804, 807 (Bd. Pat. App. Int. 1982). Hence, Applicants submit that preparation of hydroxyl-terminated polyalkylene glycol conjugates comprising a bioactive component would require only routine, and not undue, experimentation. Applicants respectfully assert that, using the guidance provided by the present specification, in view of information readily available in the art (*See e.g.*, page 5, paragraph [0009] and the Sherman Declaration), one of ordinary skill could easily make and use the presently claimed conjugates. Hence, under *Wright* and *Marzocchi*, and absent sufficient evidence to the contrary from the Examiner, Applicants respectfully submit that the presently claimed invention is fully enabled.

Therefore, in view of the teachings of the present specification and information that is known in the art (which, under *Hybritech*, *Lindemann Maschinenfabrik*, *Wands*, and *Howarth*, need not be taught in, and preferably is omitted from, the present specification), one of ordinary skill would be able to make and use the conjugates of the presently claimed invention with a reasonable expectation of success and without undue experimentation. Accordingly, Applicants respectfully submit that the present specification fully enables the full scope of the presently claimed invention. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

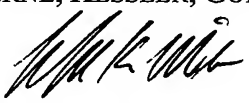
Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply are respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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